

**Remarks and Arguments:**

Claims 1-37 and 39-53 remain in this application. Claim 38 has been cancelled. Claims 1, 10, 17, 27, 36, 39-40, 44, and 49-50 have been amended.

Claim 17 stands rejected under 35 U.S.C. § 112, paragraph two, as indefinite because the claim references a drawing. Claim 17 has been amended to remove the reference to the drawing. Support for this amendment can be found in Figure 1, which displays an exponential release curve. Accordingly, favorable reconsideration and withdrawal of the rejection of claim 17 as indefinite under 35 U.S.C. §112, second paragraph is respectfully requested.

Claims 38 and 37 stand rejected under 35 U.S.C. § 112, paragraph two, as indefinite because “[b]oth claims recite ‘wherein the reaction wherein the’”. (Office Action of December 1, 2003, p. 2). Claim 38 has been cancelled. After review, it appears that Claim 37 does not recite “wherein the reaction wherein the.” Accordingly, favorable reconsideration and withdrawal of these rejections is respectfully requested.

Claim 44 stands rejected under 35 U.S.C. § 112, paragraph two, as indefinite because the claim lacked active process or method steps. Claim 44 has been amended to recite active process steps in the preparation of a burst electrode. Support for this amendment can be found in Paragraph 43. Thus, this rejection has been obviated. Withdrawal of this rejection is respectfully requested.

The remaining amendments set forth above merely define the invention more clearly. The claims as originally presented are believed to be patentable over the art cited in the subject Office Action and so are not believed to alter the original scope of the claims such as to add further patentable distinction over the art cited in the subject Office Action.

Claims 1-6, 10-14, 16-31, and 36-51 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Kinlen article. This rejection is overcome in its entirety. “To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.” *PPG Indus., Inc. v. Guardian Indus. Corp.* 75 F.3d 1558, 1566 (Fed. Cir. 1996). Kinlen only notes the usefulness of a polypyrrole/ poly(styrene sulfonate) system to release cationic biomolecules and a polypyrrole/ ATP system or a polypyrrole/ salicylate system to release anionic biomolecules. The article, first, does not disclose a burst release system and second, fails to enable one skilled in the art to make a burst electrode.

Moreover, the Office has not provided the necessary evidence or scientific reason to support its inherency argument. In *Ex parte Skinner*, 2 USPQ2d 1788, 1789 (Bd. Pat. App. & Interf. 1986) the Board stated:

[W]here an examiner has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, the examiner possesses the authority to require an applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. Nevertheless, **before an applicant can be put to this burdensome task, the examiner must provide some *evidence or scientific reasoning* to establish the reasonableness of the examiner’s belief that the functional limitation is an inherent characteristic of the prior art.** In the case before us, no such evidence or reasoning has been set forward.

(emphasis added). Here, the Office alleges that the non-Faradaic release profile claimed in the instant application is “a property of the electrode” and that “a prior art electrode...would inherent[ly] have the same property”. (Office Action of December 1, 2003, p. 3). However, the Office has not proven that non-Faradaic release is present in any prior art system. The Office has not, and cannot, put forth evidence to prove that the burst release is a necessary property of the

prior art. If a reference is silent regarding a novel characteristic of the instant application, one may resort to extrinsic evidence to prove inherency. *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 348 F.3d 992, 995 (Fed. Cir. 2003). However, this evidence must make clear that the allegedly inherent characteristic is necessarily present in the item described by the reference. *In re Oerlich*, 212 USPQ 323 (CCPA 1981); *In re Robertson*, 49 USPQ2d 1949, 1950 (Fed. Cir. 1999). If there is no reference to evidence demonstrating that a characteristic (such as burst release) is necessarily present, the Office has not carried its burden of establishing a prima facie case of anticipation by inherency. See MPEP § 2112 (placing the burden of proof on the office to provide evidence or scientific reasoning showing that the novel characteristic was inherently present in the prior art). Since the Office has not identify any reference which discloses that a burst release is necessarily present, it has not met its required burden. Thus, Applicant respectfully requests that the 35 U.S.C. § 102(b) rejection based upon Kinlen be withdrawn.

Claims 1-3, 5-8, 10, 11, 13-15, 17-19, 21-23, 27-29, 32, 33, 35-38, 40, 42, and 44-50 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Pyo et al. Pyo discloses a bilayer electrode utilizing a polypyrrole/ATP inner layer and a doped poly(N-methylpyrrole) outer layer. As with the Kinlen reference, there is no evidence of record that Pyo discloses or even suggests that its electrode is capable of a non-Faradaic burst release. According to the subject Office Action the electrodes disclosed in Pyo are inherently capable of burst release. (Office Action of December 1, 2003, p. 4). As stated above, however, the Office Action has failed to produce evidence or scientific reasoning that a bilayer electrode such as that disclosed in Pyo is necessarily capable of the burst release taught in the instant application. Thus the Office has failed to carry its prima facie burden of proving anticipation by inherency. See MPEP § 2112.

Applicant, therefore, respectfully requests that the 35 U.S.C. § 102(b) based upon Pyo be withdrawn.

Claims 1, 3-15, 17, 19-24, 27-34, 36, 37, 39 41, and 43 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Zhou et al. Zhou discloses an electrode composed of poly(N-methylpyrrole)/ poly(styrenesulfonate) capable of dopamine or dimethyldopamine release. Like Reynolds and Pyo, Zhou does not disclose burst release. In fact, the release in Zhou appears to be Faradaic. Zhou carried out experiments relating to the pulsed release of  $1H^+$  from a polypyrrole electrode, noting specifically that “[a]s time progressed, the film became depleted of  $1H^+$ , and smaller amounts were released from the 10s pulse.” (Zhou, p. 156). This suggests a more Faradaic release from the polypyrrole electrode. A burst release as disclosed in the instant application results in most of the potential total release occurring in the first and second bursts. Zhou does not disclose a similar significantly greater release in the first few pulses and the figures showing the results of this experiment do not disclose the presence of a burst release. (See Zhou, p. 156-57; Figures 4 and 5). Thus, Zhou does not disclose the burst release profile taught in the instant invention.

Moreover, the arguments related to the inherency of the Kinlen and Pyo references apply with equal force to this rejection as well. The Office has failed to produce evidence or scientific reasoning that an electrode such as that disclosed in Zhou is necessarily capable of the burst release taught and claimed in the instant application. Thus the Office has failed to carry its prima facie burden of proving anticipation by inherency. See MPEP § 2112. Applicant, therefore, respectfully requests that the 35 U.S.C. § 102(b) based upon Zhou be withdrawn.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all

presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,



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